

REMARKS

This Response is timely filed within three months of the mailing date of the latest Office Action. Accordingly, no fee is required. 37 CFR § 1.134-1.136.

Claims 1-19, and 21-32 are pending in this application, and Claim 28 is withdrawn. Claims 1, 17, and 29 are amended, and Claim 20 is canceled. Support for the amendments is found in the Specification, *inter alia*, at Paragraph [0054]. No new matter has been added. Reconsideration of the claim rejections in view of the following remarks is respectfully requested.

I. The Claims Are Not Anticipated by Box and/or Preissman

The Office rejected Claims 1-2, 4-10, 12, 14, 15-20, 29, and 31-32 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,832,692 to Box et al. (hereinafter "Box"). The Office further rejected Claims 1-2, 4-5, 10, 12-19, 21-25, and 29-32 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,383,190 to Preissman (hereinafter "Preissman"). Applicant respectfully traverses these rejections.

As amended, Claim 1 recites a system for percutaneous delivery of bone cement during a surgical procedure, comprising: a plunger assembly, comprising: a shaft having a first end, a middle section, and a second end, wherein the middle section is threaded; and a handle attached to the first end of the shaft; a dispenser hub assembly around the shaft, the dispenser hub assembly having a collar and a hand-grip attached to the collar, and a threaded portion formed on an interior surface of the collar; and a hollow tube pre-filled with the bone cement for use during the surgical procedure having a first end and a second end, said first end of said hollow tube adapted to be removably

engaged with the dispenser hub assembly, wherein the shaft is axially displaceable through the hollow tube for controlled displacement of the bone cement through the second end of the hollow tube. Claims 2-16 depend from Claim 1 and include at least all of the limitations set forth therein.

As amended, Claim 17 recites a cement dispensing apparatus for percutaneous delivery of bone cement from a disposable hollow tube to a patient during a surgical procedure, the apparatus comprising: actuation means, comprising: a shaft having a first end, a middle section, and a second end; and a handle attached to the first end of the shaft; a dispenser hub assembly, around the shaft of the actuation means, the dispenser hub assembly having a collar and a hand-grip attached to the collar, the collar being adapted to receive the disposable hollow tube; and a release assembly disposed in a void formed in the dispenser hub assembly for controlling the axial displacement of the shaft through the disposable hollow tube, wherein the release assembly comprises a trigger having a threaded portion for releasably engaging said shaft; and a spring having a first end in contact with said trigger and a second end in contact with said dispenser hub assembly, wherein the bias of said spring causes said trigger to engage said shaft. Claims 18 and 19 depend from Claim 17 and include at least all of the limitations set forth therein.

Claim 21 recites a multi-use cement dispenser kit, comprising: cement delivery means for delivering bone cement into a patient during a surgical procedure, the cement delivery means comprising: a plunger assembly, having a shaft and a handle attached to one end of the shaft; and a dispenser hub assembly, around the shaft of the plunger

assembly; and at least one tube pre-filled with bone cement for use during the surgical procedure, the tube adapted to be removably attached to the dispenser hub assembly, wherein the shaft of the cement delivery means is axially displaceable through the tube for controlled displacement of the bone cement through the tube. Claims 22-27 depend from Claim 21 and include at least all of the limitations set forth therein.

As amended, Claim 29 recites a system for percutaneous delivery of bone cement during a surgical procedure, comprising: a plunger assembly, comprising a shaft having a first end, a middle section, and a second end; and a handle attached to the first end of the shaft; a dispenser hub assembly disposed around the shaft, the dispenser hub assembly having a collar and a hand-grip attached to the collar; and a hollow tube pre-filled with the bone cement for use during the surgical procedure having a first end and a second end, the first end of the hollow tube adapted to be removably engaged with the dispenser hub assembly, wherein the shaft is axially displaceable through the hollow tube for controlled displacement of the bone cement through the second end of the hollow tube.

Claim 30 recites a system for percutaneous delivery of bone cement during a surgical procedure, comprising: a plunger assembly, comprising: a shaft having a first end, a middle section, and a second end, wherein the middle section is threaded; and a handle attached to the first end of the shaft; a dispenser hub assembly around the shaft, the dispenser hub assembly having a collar and a hand-grip attached to the collar, and a threaded portion formed on an interior surface of the collar; and a hollow tube for containing bone cement during the surgical procedure having a first end and a second

end, the first end of the hollow tube adapted to be removably engaged with the threaded portion of the dispenser hub assembly, wherein the hollow tube includes a funnel-shaped opening at the first end for facilitating the receipt of the bone cement in the hollow tube, and wherein the shaft is axially displaceable through the hollow tube for controlled displacement of the bone cement through the second end of the hollow tube.

Preissman does not disclose the claimed subject matter of the present application. Although Preissman discloses a pressure applicator for delivering an implant material, Preissman fails to teach every feature of the claimed invention. With respect to Claims 1, 17, 21, 29 and 30, Preissman does not disclose a dispenser hub assembly around a shaft, having a collar, a hand-grip attached to the collar, and a hollow tube adapted to be removably engaged with the dispenser hub assembly. The column **74'** disclosed in Preissman is formed integrally with the handle **75** and is not adapted to be removably engaged with a dispenser hub assembly. See Preissman, Fig. 11; Col. 12, ll. 12-56. Moreover, Preissman does not disclose a hollow tube pre-filled with bone cement, as presently claimed. With respect to Claim 17, Preissman also fails to disclose or suggest a release assembly disposed in a void formed in a dispenser hub assembly, as presently claimed.

Further, Box does not teach the claimed subject matter of the present application. Box is directed to an inflation device for inflating and deflating an angioplasty balloon. See Box, Col. 1, ll. 8-14. With respect to Claims 1 and 29, Box does not disclose a system for percutaneous delivery of bone cement during a surgical procedure. The Office states that the "introductory statement and all other functional

statements of intended use” in the claims are deemed not to impose limitations on the claims distinguishable over Box. Claims 1 and 29, however, recite a hollow tube pre-filled with bone cement. Box does not disclose or suggest such a hollow tube. Rather, the syringe assembly disclosed in Box is adapted to be filled with fluids appropriate for inflating the balloon, such as a mixture of saline solution and contrast media. See Box, Col. 6, ll. 1-10. With respect to Claim 17, Box does not disclose a release assembly disposed in a void formed in a dispenser hub assembly, as presently claimed.

The present Office Action does not reject independent Claim 30 under Section 102, however, the Examiner states that claims 31-32, which depend from, and necessarily include all of the limitations of, Claim 30 *are* rejected under Section 102. As this rejection is in error, Applicant respectfully requests withdrawal of the rejection of claims 31-32. Nevertheless, as discussed below, Box alone or in combination with another reference does not teach or suggest the subject matter claimed in Claims 30-32.

For at least these reasons, Applicant respectfully submits that Box and Preissman, taken alone or in combination, fail to disclose Applicant's claimed invention. Accordingly, Applicant requests reconsideration and withdrawal of the rejections.

II. The Claims are Non-Obvious

Claims 3 and 30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Box and in view of U.S. Patent 6,019,765 to Thornhill et al. (hereinafter “Thornhill”). Claim 11 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Box. Claim 13 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Box in view

of U.S. Patent No. 4,312,343 to LeVeen et al. (hereinafter "LeVeen"). Claim 14 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Box in view of U.S. Patent No. 5,603,701 to Fischer (hereinafter "Fischer"), and over Preissman in view of Fischer. Claims 21-27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,395,007 to Bhatnagar et al. (hereinafter "Bhatnagar") in view of Preissman. Applicant respectfully traverses these rejections.

Taken alone or in combination, neither Box nor Thornhill teach the subject matter claimed in the present application. Box is directed to an inflation device for inflating and deflating an angioplasty balloon. See Box, Col. 1, ll. 8-14. Box does not suggest a system for percutaneous delivery of bone cement during surgical procedure. Moreover, Box fails to disclose or suggest a hollow tube for containing bone cement, wherein the hollow tube includes a funnel-shaped opening for facilitating the receipt of the bone cement. Thornhill is directed to a bone allograft applicator device. The Thornhill device, however, fails to teach or suggest the elements of the claimed invention. Thornhill discloses a loading component **200** that may be temporarily attached to the cavity **104** prior to use of the device. Thornhill does not disclose a hollow tube that *includes* a funnel-shaped opening. Moreover, Thornhill does not teach a dispenser hub assembly, or a hollow tube for containing bone cement, as presently claimed.

In order to establish a *prima facie* showing of obviousness under Section 103, the Examiner must set forth three basic criteria. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the

reference teachings. See MPEP §§ 706.02(j), 2142 (8th ed., 2nd Rev., 2004). Second, there must be a reasonable expectation of success. *Id.* Finally, the prior art reference (or the references when combined must teach or suggest all of the claim limitations. *Id.*

With respect to Claim 30, the Examiner fails to establish a *prima facie* showing of obviousness. The Examiner has failed to provide any meaningful explanation of the required motivation for combining Box and Thornhill. The required motivation is presumed in the latest Office Action from the mere fact that Box and Thornhill each disclose a syringe and “that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a funnel-shaped opening to a distal end of the Box syringe. . .for ease of placement of material within the Box syringe.” This assertion, however, does not provide the required motivation. Box and Thornhill are directed to entirely different medical fields, and are classified in entirely different areas of the USPTO database. The only apparent motivation for combining the references arises from Applicant’s disclosure and the claimed invention itself, which constitutes impermissible hindsight motivation and cannot be relied upon as a reason to combine references. See, e.g., *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

Further, although Thornhill discloses a loading component **200** to facilitate placement of a bone graft slurry, there is not a reasonable expectation of success in the combination of Box and Thornhill. Box discloses a syringe assembly designed to provide the requisite mechanical advantage for inflating a balloon catheter to higher pressures, such as on the order of 450 psi and above. See Box, Col. 1, ll. 46-64.

Thornhill discloses that “[a]fter a desired amount of slurry is placed within the device, the funnel **200** is removed from the hollow member **102**.” See Thornhill, Col. 4, ll. 34-36. As such, the Thornhill device would not operate properly with a hollow tube having a funnel-shaped opening. Because Thornhill clearly discloses that the device does not operate with a funnel-shaped opening, there is no basis for a reasonable expectation of success that Box would operate properly when combined with the loading component of Thornhill, particularly with the specific pressure requirements of the Box device.

With respect to Claim 21, taken alone or in combination, neither Bhatnagar nor Preissman teach or suggest the claimed subject matter. Although Preissman discloses a pressure applicator for delivering an implant material, Preissman fails to teach every feature of the claimed invention. Preissman does not disclose a dispenser hub assembly around a shaft, nor at least one tube pre-filled with bone cement, as presently claimed. Moreover, Preissman is silent as to the use of a multi-use kit for delivery of bone cement. Although Bhatnagar teaches the use of a kit including an injection device, Bhatnagar fails to teach the elements of the claimed invention. The Examiner states that Bhatnagar discloses that “any cement delivery means could be used.” This assertion is insufficient to render the claimed subject matter obvious. Bhatnagar fails to teach a dispenser hub assembly and tube adapted to be removably attached to the dispenser hub assembly, as presently claimed. Moreover, despite the use of multiple references, the Examiner fails to present a single reference which discloses or even suggests a kit having at least one tube pre-filled with bone cement for use during a surgical procedure. It is well established that a prior art reference or combination of

references must teach or suggest all of the claim limitations. Accordingly, Preissman and Bhatnagar fail to establish a *prima facie* showing of obviousness.

In view of the foregoing, Applicant submits that the cited references do not teach or suggest the claimed subject matter and respectfully requests withdrawal of the rejections of the Claims under Section 103.

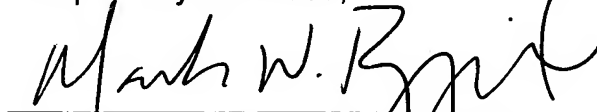
III. Conclusion

Applicant respectfully submits that the Claims of the present invention define patentable subject matter and that the application is in condition for allowance. Should the Examiner believe that anything further is desirable to place the application in better condition for allowance, the Examiner is invited to contact Applicant's undersigned attorney at the below listed telephone number.

It is believed that no fee is required for the present amendment. In the event that a fee is required, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to deposit account number 03-2469. Moreover, if the deposit account contains insufficient funds, the Commissioner is hereby invited to contact Applicant's undersigned representative to arrange payment.

Dated: JULY 1, 2005

Respectfully submitted,



JOHN N. COULBY, Reg. No. 43,565
MARK W. RYGIEL, Reg. No. 45,871
COLLIER SHANNON SCOTT, PLLC
3050 K Street, N.W., Suite 400
Washington, D.C. 20007
(202) 342-8400